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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,306	09/28/2005	Danila Valmori	LUD 5739 US (10201468)	6397
24972 7590 05/02/2007 FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			EXAMINER AUDET, MAURY A	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 05/02/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/523,306

Applicant(s)

VALMORI ET AL.

Examiner

Maury Audet

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1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 2, 4-5, and 8-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6-7 is/are rejected.
- 7) ☒ Claim(s) 1, 3, 6-7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on N/A is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-7, as drawn to a peptide consisting of SEQ ID NO: 1, in the reply filed on 2/28/07 is acknowledged. Claims 2, 4-5, and 8-13 are withdrawn from consideration as being drawn to non-elected subject matter (claims 14-25 were previously cancelled by amendment on 1/31/05). Claims 1, 3, and 6-7 are examined on the merits as being drawn to the elected peptide consisting of SEQ ID NO: 7.

Drawings

The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention; namely Figures 1-4B (see e.g. specification pages 5 and 8). Applicant is required to furnish the drawings under 37 CFR 1.81. However, no new matter may be introduced in the required drawing (e.g. beyond that expressed in the specification or in provisional application S.N. 60/400,076). Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

Specification

The disclosure is objected to because of the following informalities:

1. What should be pages 1, 9, and 17 of the specification do not contain page numbers at the bottom, like the remainder of the specification.

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2. The specification at e.g. pages 5 and 8 references Figures 1-4B; however, no Figures/Drawings have been found in the application as filed, nor by continuity in PCT/US03/023306.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, and notwithstanding that the elected invention is to a peptide consisting of SEQ ID NO: 1 (which is complexed with an MHC molecule), claim 1 is presently drawn to “the peptide who amino acid sequence consists of SEQ ID NO: 17, with the proviso that said peptide is not the peptide of SEQ ID NO: 17”. An invention to the above, based on the recited transition phrase (consisting of), is not possible since a peptide that consists of SEQ ID NO: 17 MUST be SEQ ID NO: 17. Namely SEQ ID NO: 17 is drawn to “Ala Ala Ser Glu Lys Ile Phe Tyr Val”, while e.g. elected SEQ ID NO: 1 is drawn to “Ala Ala Ala Pro Lys Ile Phe Tyr Ala”. SEQ ID NO: 17 does not consist of SEQ ID NO: 1, they are distinct peptides, the a modified derivative of the former. It is suggested, as is required based on elected, that the claims simply be amended to “a peptide consisting of SEQ ID NO: 1”.

In claim 1, the invention is unclear. Namely, the claimed subject matter is to:

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“an isolated peptide [consisting of SEQ ID NO: 1] which binds to an Major Histocompatibility Complex (MHC) molecule [MHC assumed to be, see below] to form a complex that is recognized by a cytotoxic T cell which recognizes and lyses cells presenting complexes of Human Leukocyte Antigen-A2 (HLA-A2) molecules [HLA-A2 assumed to be, see below]”.

Is an MHC molecule synonymous with HLA-A2 molecules? Or do HLA-A2 molecules express MHC molecules? What is the connection between SEQ ID NO: 1 complexed with an MCH molecule and ultimately HLA-A2 being recognized by a cytotoxic T cell? Such was not clearly defined in the specification, and the claims have not been distinctly claimed such that the invention/structure/interaction of compounds is clear. [It is noted that MHC molecules are known to present themselves on cells of various origin, and that the invention is to any such molecules to which a peptide consisting of SEQ ID NO: 1 may bind. The breadth in terms of binding any MHC molecule is deemed accepted as both definite/understood by the one of ordinary skill in the art and supported both by the specification and what is known in the art as to MHC molecules).

Claim Objections

Claims 1, 3, 6, and 7 are objected to because of the following informalities:

1. For clarity, the first recitation of MHC should begin with the full name followed by the mnemonic in parenthesis (assumed to be Major Histocompatibility Complex (MHC)). No definition was found in the specification, but a search of the Online Medical Dictionary resulted in the above-accepted meaning. <http://cancerweb.ncl.ac.uk/cgi-bin/omd?query=mhc>.

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2. Likewise, for clarity, the first recitation of HLA-A2 should begin with the full name followed by the mnemonic in parenthesis (assumed to be Human Leukocyte Antigen-A2 (HLA-A2)). No definition was found in the specification, but a search of the Online Medical Dictionary resulted in the above-accepted meaning. <http://cancerweb.ncl.ac.uk/cgi-bin/omd?query=hla>.

Appropriate correction is required.

The prior art of record was not found to reasonably teach or suggest the artificial sequence of SEQ ID NO: 1. Were the claims amended commensurate in scope with the elected invention (e.g. "an isolated peptide consisting of SEQ ID NO: 1 which binds . . .) and the rejections/objections above successfully traversed by argument/amendment, the claims would likely receive favorable consideration. Claims 6-7 may be cancelled without prejudice, since amendment to elected SEQ ID NO: 1 would not further limit base claim 1.

Conclusion

No claims are allowed.

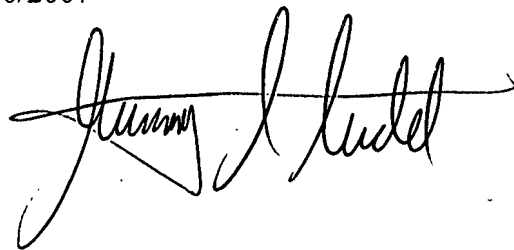
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 04/30/2007

A handwritten signature in black ink, appearing to read "Maury Audeter", written over a horizontal line.

MAURY AUDETER
PATENT EXAMINER